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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,264	04/08/2004	John P. Mullally	MUJ-104-A-1	7507

7590 03/19/2008  
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EXAMINER
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WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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03/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,264	<b>Applicant(s)</b> MULLALLY, JOHN P.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 20 is/are pending in the application.
- 4a) Of the above claim(s) 10 - 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 9, 18 - 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I in the reply filed on January 7, 2008 is acknowledged.
2. Claims 10 – 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Applications No. 60/482,574, 60/453,917, 60/461,534 and 10/978,117, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Each of these disclosures lists a variety of conditions that may be treated with the compositions of the instant invention but does not indicate the treatment of vision or disorders of the eye. For example, in 11/798,117, the list of disorders contemplated appears in paragraph [0030] and does not disclose any conditions related to the eye. The closest disorder appears to be sinusitis. However, otherwise no indication of treatment of disorders related to the eye or improving vision can be found in the specification of these applications.

If Applicant is in disagreement with the Examiner regarding the not granting of the priority date, Applicant is respectfully requested to point by page and line number wherein support may be found for the instant invention.

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed provisional application No. 60/453,917 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current

Art Unit: 1618

application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed provisional application is improper.

Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

### ***Specification***

5. The disclosure is objected to because of the following informalities: the serial number of the prior-filed application is incorrect. The serial number appearing in the first paragraph of the specification is 10/798,017, which relates to a check multifeed detection apparatus. It is believed that the correct application number is 10/798,117.

Appropriate correction is required.

### ***Claim Objections***

6. Claims 5, 6 and 20 are objected to because of the following informalities: It appears that applicant wished to include the antihistamine loratadine in claims 5 and 20, but has apparently been misspelled as "lortadine". In claim 6, it appears that "monohydrate" has been misspelled as "mononhydrate".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 – 9 and 18 – 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of improving vision by treating iritis, glaucoma or other ocular hypertensive disorders, does not reasonably provide enablement for all methods by which vision can be improved. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples
6. The quantity of experimentation necessary;

7. The state of the prior art; and
8. The relative skill of those skilled in the art.

Each factor is address below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention: a method of improving the vision of a user by administration of a composition comprising a leukotriene inhibitor, an antihistamine, a corticosteroid or mixtures (including all three ingredients).

2. The breadth of the claims: All types of improving vision are encompassed. "Improving vision" is a broad term that can encompass correction of myopia, hyperopia, astigmatism, relief of irritation to the eye caused by a variety of sources, and correction of glaucoma, cataracts or retinal tearing. It could also encompass having better night-vision. The claims contain language towards the mechanism by which the vision is improved (a reduction in C-reactive protein levels).

3. The amount of direction or guidance presented, the presence or absence of working examples: One example (p 6 of the instant specification) is provided in which the myopia of diabetic patient is improved over a period of 5 weeks. While specific trademark names are provided for the three components administered, no information as to the dosage of these ingredients is in the method. The given information is one

Art Unit: 1618

daily dosage for the leukotriene inhibitor and antihistamine and “two daily infusions of from 1 to 4 squeezes” of the corticosteroid component so the amount of active ingredient used in the method cannot be determined.

4. The quantity of experimentation necessary, the state of the prior art, the predictability or unpredictability of the art, and the relative skill of those skilled in the art: the relative skill of those skilled in the art is high. The different types of vision problems (glaucoma, retinal tearing, myopia, etc.) have a variety of causes and symptoms. The art recognizes that compositions of the ingredients listed can be used in the treatment of iritis (US Patent 5,998,454) or glaucoma and other disorders associated with ocular hypertension (US Patent 5,602,143, col 1, ln 64 – 66; col 6, ln 56 – 58). Myopia is often caused by the length of the eye no matching the focal length of the incoming light or refractive problems that cause the light not to focus on the retina. There is no indication in the prior art that compositions comprising these ingredients are capable of changing the length of the eyeball or the refractive properties of the eye such that the focal length of the incoming light matches the length of the eye. Therefore, Applicant is enabled for those improvements of vision that are recognized by the art as treatable by a leukotriene inhibitor, an antihistamine and/or a corticosteroid, namely iritis, glaucoma, and ocular disorders associated with ocular hypertension, but not all ways in which vision may be improved.



***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Paragraph***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2 – 7, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In independent claim 1, only one ingredient from classes (a) – (c) is required although mixtures are also encompassed. In claim 2, it is unclear whether Applicant is refining the ranges of the amounts of the ingredients from each class that may be present in the selected composition or if, because of the “and” at the end of line 3, one ingredient from each class (a) – (c) must be present in the dosage ranges presented. If the latter interpretation is used, then claim 8 fails to further the claim from which it depends. For the purposes of applying art, claim 2 will be interpreted as only limiting the dosages of those compounds that may be present in the composition and that the dosage ranges must be met for all three classes of compounds in the same composition in dependent claim 8.

11. Claims 2 – 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims, the units for the amount of corticosteroid are “µcg”. In the metric system, only one prefix is used as the multiplier to

Art Unit: 1618

denote the relationship to the base unit. It is unclear how 1  $\mu\text{cg}$  is related to 1 gram or 1 milligram.

12. Claims 1 – 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "highly sensitive C-reactive protein" in claim 1 is a relative term which renders the claim indefinite. The term "highly sensitive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear whether all C-reactive proteins are highly sensitive, or if different classes of C-reactive protein exist, some of which are more sensitive than others.

13. Claims 1 – 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the limitation "at least about 2 days". "At least" is a minima and all possible values above 2 days are encompassed. "About" indicates a range centered on the recited value. In this case, values both above and below 2 days. Therefore, what values are included in the range "at least about 2 days" cannot be determined.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Fleisch et al. (US Patent 5,998,454, entire document).

Fleisch describes a method using leukotriene antagonists (inhibitors) to treat iritis which is characterized by excessive release of leukotriene (p 13, ln 17 – 20). Acute iritis (inflammation of the iris, col 1, ln 21) can be associated with photophobia and moderately decreased vision (col 14, ln 45 – 46). Intraocular inflammation may lead to more serious, structural changes in the eye such as cataracts, glaucoma and synchia (col 1, ln 16 – 19).

Fleisch discloses a method of improving vision by treating iritis, a condition than can be associated with moderately decreased vision, with a leukotriene inhibitor. As the same class of compounds (leukotriene inhibitors) will act on the same pathway as in the

Art Unit: 1618

claims of the instant application, the method of the prior art will inherently result in a decrease in C-reactive protein.

16. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Krauss (US Patent 5,602,143, entire document).

Krauss discloses a composition of LY-83583 that is administered to a subject to decrease the intraocular pressure (col 6, ln 26 – 63). This composition can be used to treat not only glaucoma but other ocular hypertensive disorders (col 6, ln 56 – 58). LY-83583 is an inhibitor of antigen-induced leukotriene release (a leukotriene inhibitor; col 1, ln 64 – 66). The composition is administer one or twice daily (col 5, ln 24 – 27) and is therefore administered for more than one day, meeting the limitation of being administered for at least 2 days. As the same class of compounds (leukotriene inhibitors) will act on the same pathway as in the claims of the instant application, the method of the prior art will inherently result in a decrease in C-reactive protein. As the same steps are followed (taking the composition for at least 2 days), the same result, improving the vision, must occur.

17. Claims 1 and 18 rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Chang et al. (US Patent 6,635,654, entire document).

Chang et al. discloses an ophthalmic composition of loratadine for relieving ocular allergies (col 1, ln 6 – 12). This condition is characterized by redness, itching and swelling of the eyes (col 1, ln 14 – 15). Relief of these symptoms will improve the vision

Art Unit: 1618

of the user. Application of the composition will occur one or more times daily while the condition persists (col 5, ln 30 – 31). Thus, the compound is administered on a daily basis for a period of at least 1 day, anticipating the period of at least about 2 days in claim 1. As the same class of compounds (antihistamines) will act of the same pathway as in the claims of the instant application, the method of the prior art will inherently result in a decrease in C-reactive protein. As the same steps are followed (taking the composition for at least 2 days), the same result, improving the vision must occur.

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1618

20. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454)

As discussed above, Fleisch et al. discloses that iritis of the eye can be accompanied by moderately decreased vision that can be treated with leukotriene inhibitors. Fleisch also states that once diagnosed, it is imperative to treat with corticosteroids, although this use should be closely monitored due to ominous side effects (col 1, ln 28 – 31). While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitors). Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

Fleisch et al. does not specifically exemplify a treatment protocol to treat iritis using both a leukotriene inhibitor and a corticosteroid.

It would have been obvious to one of ordinary skill in the art to use a combination of a leukotriene inhibitor and a corticosteroid as both ingredients are exemplified to treat iritis. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

21. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454) in view of Chang et al. (US'654).

As discussed above, Fleisch et al. discloses that iritis of the eye can be accompanied by moderately decreased vision that can be treated with leukotriene inhibitors and corticosteroids. That composition can be administered on a daily basis for a period of at least two days. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitors and corticosteroids). Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein. The cause of the iritis being treated may be allergies (col 1, ln 21 – 23).

Fleisch et al. does not teach the use of antihistamines for the treatment of iritis.

Chang et al. discloses that the antihistamine loratadine may be useful for the treatment of ocular allergies (col 1, ln 8 – 11), a similar reaction to the allergic reactions that occur in the sinuses, nose or lung (col 1, ln 15 – 19). Application of the composition will occur one or more times daily while the condition persists (col 5, ln 30 – 31). Thus, the compound is administered on a daily basis for a period of at least one day.

One of ordinary skill in the art would be motivated to prepare a composition comprising a corticosteroid, a leukotriene inhibitor and a corticosteroid (disclosed by Fleisch et al. to treat iritis), further comprising the anti-histamine loratadine (taught by Chang et al. to treat one underlying cause of iritis). The method taught by Fleisch et al. treats a symptom while the method of treating an underlying cause is taught by Chang et al. One of ordinary skill would realize that while the symptoms of a disease or condition can be treated, the underlying cause(s) should, if possible, also be treated. The resulting improvement in vision, from the treating of the allergies that can underlie

iritis and the symptoms of the iritis itself, can be accomplished with a composition comprising a leukotriene inhibitor, an antihistamine and a corticosteroid. As the same steps are followed (taking the composition for at least 2 days), the same result, improving the vision must occur.

22. Claims 1 – 3, 5, 7, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454) and Chang et al. (US'654) in view of Weinstein et al. (US Patent 6,521,254).

As discussed above, the combination of Fleisch et al. and Chang et al. teaches a composition comprising a leukotriene inhibitor, a corticosteroid and an antihistamine. That composition can be administered on a daily basis for a period of at least two days. This composition can then be used in a method of treating iritis of the eye and therefore improving vision. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

Neither Fleisch et al. nor Chang et al. discloses dosing amounts in grams or milligrams for the antihistamine.

Weinstein et al. discloses that the amount of antihistamines as required by the FDA to state that a product has therapeutic effectiveness over a 24-hour period varies widely depending on active ingredient. For some specific antihistamines, those amounts



Art Unit: 1618

are 5 mg of cetirizene, 10 mg of loratadine and 180 mg of fexofenadine (col 5, ln 8 – 12).

It would have been obvious to one of ordinary skill to use the dosage information presented in Weinstein et al. to determine the amount of the antihistamine present in the composition that is used to improve the vision of a patient taught by Fleisch et al. and Chang et al., which lacked information regarding appropriate dosages. As the same steps are followed (taking the composition for at least 2 days), the same result, improving the vision and a decrease in C-reactive protein, must occur. The amount of these ingredients in Weinstein et al. represents the amounts of various antihistamines that can be safely administered to a subject and as such information is important when preparing a composition to be administered, it would be obvious to use the teachings of Weinstein to provide the dosing amounts.

23. Claims 1 – 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454) and Chang et al. (US '654) further in view of Down (PGPub 2003/0096840).

As discussed above, Fleisch et al. and Change et al. teach the use of both a corticosteroid and a leukotriene inhibitor in a method of treating iritis. The composition can be administered on a daily basis for a period of at least two days. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). As the same steps are followed (taking the

composition for at least 2 days), the same result, improving vision must occur. Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

Neither Fleisch et al. nor Chang et al. describe the dosage in milligrams or grams of the leukotriene inhibitor.

Down discloses the leukotriene inhibitor montelukast sodium (paragraph [0001]) will generally be administered in a unit dose comprising about 2 to about 20 mg (paragraph [0008]).

It would have been obvious to one of ordinary skill to use the dosage information presented in Down for the amount of the leukotriene present in the composition that is used to improve the vision of a patient taught by Fleisch et al. and Chang et al., which lacked information regarding appropriate dosages. The amount of these ingredients in Down represents an amount of one leukotriene inhibitor that can be safely administered to a subject and as such information is important when preparing a composition to be administered, it would be obvious to use the teachings of Down to provide the dosing amounts.

24. Claims 1, 2, 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. and Chang et al. as applied to claims 1 and 18 above, and further in view of Dal Negro et al. (Pul Pharm Ther, 2003).

As discussed above, Fleisch et al. and Chang et al. teaches the use of both a corticosteroid and a leukotriene inhibitor in a method of treating iritis. The composition can be administered on a daily basis for a period of at least two days. While a decrease

in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). As the same steps are followed (taking the composition for at least 2 days), the same result, improving vision must occur. Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

Fleisch et al. and Chang et al. do not describe the dosage of the corticosteroid in  $\mu\text{cgs}$ .

Dal Negro et al. discloses a study in which patients were treated with a combination of salmeterol and fluticasone in amount of 50/250  $\mu\text{cg}$  twice a day (bid) (abstract methods section, p 241). Therefore the prior art teaches that a safe and effective dosage of the corticosteroid is about 110  $\mu\text{cg}$  to about 220  $\mu\text{cg}$  claimed in the instant application.

It would have been obvious to one of ordinary to skill to use the dosage information presented in Dal Negro et al. as a starting point in the optimization of the amount of the active ingredient (the results effective parameter) present in the composition that is used to improve the vision of a patient taught by Fleisch et al., which lacked information regarding appropriate dosages. It is generally desirable to use as little active ingredient as possible but still achieve therapeutic treatment of the desired composition. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05.**

Art Unit: 1618

25. Claims 1, 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al., Chang et al. and Dal Negro et al. (Pul Pharm Ther, 2003) as applied to claims 1, 2, 3 and 7 above and further in view of Bardsley et al. (US Patent 6,677,326).

The combination of Fleisch et al., Chang et al. and Dal Negro et al. teaches a composition for the treatment of iritis comprising a leukotriene inhibitor and a corticosteroid such as fluticasone that can be administered in an amount of about 110 to about 220 µcg. That composition can be administered on a daily basis for a period of at least two days. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). As the same steps are followed (taking the composition for at least 2 days), the same result, improving vision must occur. Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

Neither Fleisch et al., Chang et al. or Dal Negro et al. exemplify mometasone furoate monohydrate, triamcinalone, acetonide, budesonide or azelastine as corticosteroids.

Bardsley et al. discloses that budesonide and fluticasone are both corticosteroids (col 2, ln 58 – 61) that may have different potencies (col 1, ln 61 – 62).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use budesonide as the corticosteroid in the method of treating iritis taught by Fleisch et al. Bardsley teaches that fluticasone and budesonide are functional

Art Unit: 1618

equivalents of each other and as a starting point, similar amounts of budesonide and fluticasone would be a starting point for optimization of the amount of corticosteroid present in the composition used to treat iritis. It would have been obvious to one of ordinary skill to optimize the amount of the active ingredient present (the results effective parameter) when replacing one corticosteroid with another corticosteroid.

26. Claims 1 – 5, 7 – 9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454), Chang et al. (US'654), Weinstein et al. (US'254) as applied to claims 1 – 3, 5 and 17 – 19 above and further in view of Down (PGPub'840) and Dal Negro et al.

The combination of Fleisch et al., Chang et al and Weinstein et al. discloses a composition for the treatment of iritis that comprise a leukotriene inhibitor, a corticosteroid and an antihistamine (whose dosage information is disclosed by Weinstein et al.). Weinstein et al. also discloses that antihistamines can be administered orally (col 1, ln 25 – 27). That composition can be administered on a daily basis for a period of at least two days. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). As the same steps are followed (taking the composition for at least 2 days), the same result, improving vision must occur. Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

None of the references (Fleisch et al, Chang et al., or Weinstein et al.) disclose dosage amounts for the antihistamine or corticosteroid components in grams or milligrams or the nasal administration of the corticosteroid.

Down discloses the leukotriene inhibitor montelukast sodium (paragraph [0001]) will generally be administered in a unit dose comprising about 2 to about 20 mg (paragraph [0008]). The leukotriene inhibitor can be administered orally (abstract).

Dal Negro et al. discloses a study in which patients were treated with a combination of salmeterol and fluticasone in amount of 50/250 µcg twice a day (bid) (abstract methods section, p 241). The drug is administered via an inhaler, a way in which a steroid is infused to the nasal passages (p 242, col 2 paragraph 1).

It would have been obvious to one of ordinary skill in the art to prepare a composition for the treatment of iritis comprising a leukotriene inhibitor, an antihistamine and a corticosteroid (the combined teachings of Fleisch et al. and Chang et al.). As no dosing information is provided for any of the drugs, one of ordinary skill would have used the disclosure of Weinstein et al. to determine the amount of antihistamine (which also can be administered orally) in the composition, Dal Negro et al. for the amount of the nasally administered corticosteroid fluticasone and Down for the amount of leukotriene inhibitor (which can be administered orally) to use in the composition. The amount of these ingredients in Down and Dal Negro et al. represent an amount of active ingredient of that class that can be safely administered to a subject and as such information is important when preparing a composition to be administered, it would be

obvious to use the teachings of Down and Dal Negro et al. to provide the dosing amounts.

27. Claims 1, 2, 6, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleisch et al. (US'454), Chang et al. (US'654), Weinstein et al. (US'254), Down (PGPub'840) and Dal Negro et al. as applied to claims 1 – 5, 7 – 9, 18 and 19 above further in view of Bardsley et al. (US Patent 6,677,326).

The combination of Fleisch et al. Chang et al and Weinstein et al. discloses a composition for the treatment of iritis that comprise a leukotriene inhibitor (whose dosage information is disclosed by Down), a corticosteroid (fluticasone, whose dosage information is disclosed by Dal Negro et al.) and an antihistamine (whose dosage information is disclosed by Weinstein et al.). That composition can be administered on a daily basis for a period of at least two days. While a decrease in C-reactive protein is not disclosed by the prior art, the composition used in both methods has components from the same class of compounds (leukotriene inhibitor, a corticosteroid and an antihistamine). As the same steps are followed (taking the composition for at least 2 days), the same result, improving vision must occur. Thus, the improvement in vision must be accompanied by a decrease in C-reactive protein.

None of these references exemplify mometasone furoate monohydrate, triamcinalone, acetoniode, budesonide or azelastine as corticosteroids.

Bardsley et al. discloses that both budesonide and fluticasone are both corticosteroids (col 2, ln 58 – 61) that may have different potencies (col 1, ln 61 – 62).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use budesonide as the corticosteroid in the method of treating iritis using a composition comprising a leukotriene inhibitor (whose dosage information is disclosed by Down), a corticosteroid (whose dosage information is disclosed by Dal Negro et al.) and an antihistamine (whose dosage information is disclosed by Weinstein et al.). Bardsley teaches that fluticasone and budesonide are functional equivalents of each other and as a starting point, a similar amount of budesonide as fluticasone would be a starting point for optimization of the amount of corticosteroid present in the composition used to treat iritis. It would have been obvious to one of ordinary skill to optimize the amount of the active ingredient present when changing from one corticosteroid to another and make a composition comprising budesonide as the corticosteroid.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1618

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NMW